

REMARKS

Claims 1-20 and 23-57 are pending in the application.

Claims 4, 7, 15, 17, 18, 26, and 29 have been amended herein with regard to claim dependency. Accordingly, no new matter has been added by these amendments.

New claims 58-100 have been added in this application. These claims are based on the dependent claims currently present in the application. Therefore, support for these new claims is the same as for the original previously presented dependent claims and can be found throughout the specification and in the original claims. Accordingly, Applicant respectfully submits that no new matter has been added by these new claims.

After entry of this amendment, claims 1-20 and 23-100 will be pending in the application.

Applicant respectfully requests that the Examiner initial and return a copy of the PTO Form 1449 submitted with the Supplemental Information Disclosure Statement filed September 30, 2004.

Applicant notes that there were four pages of material attached to the Office Action dated December 23, 2004 that do not appear to relate to the instant application. These papers appear to relate to a German language document DE 43 18 692 A1. Applicant respectfully requests clarification regarding whether these papers were erroneously attached to the Office Action.

The remaining outstanding rejections are addressed below.

- 1. Obviousness-type double patenting rejection of claims 12-20, 39-43, 50, 53, and 56 has been overcome.**

Claims 12-20, 39-43, 50, 53, and 56 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-31 of U.S. Patent No. 6,624,293 in view of U.S. Patent No. 5,271,941, Prewett *et al.* (1996), and U.S. Patent No. 5,658,947.

Although Applicant does not acquiesce in the rejection or the characterization of the cited references, in order to expedite prosecution Applicant encloses herewith a terminal disclaimer over U.S. Patent No. 6,624,293.

In view of this submission, Applicant respectfully requests that this rejection be reconsidered and withdrawn.

2. Obviousness-type double patenting rejection of claims 1-20 and 23-57 has been overcome

Claims 1-20 and 23-57 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-14 of copending Application Ser. No. 10/641,521 in view of U.S. Patent No. 5,271,941, Prewett *et al.* (1996), and U.S. Patent No. 5,658,947.

At the outset, Applicant notes that claims 1-14 of copending Appln. Ser. No. 10/641,521 are solely directed to method claims. Accordingly, Applicant submits that this rejection is inappropriate with regard to at least claims 12-20, 39-43, 50, 53, and 56 of the instant application, which are directed to various embodiments of a pharmaceutical composition.

Although Applicant does not acquiesce in the rejection or the characterization of the cited references, in order to expedite prosecution Applicant encloses herewith a terminal disclaimer over copending Application Ser. No. 10/641,521. Accordingly, Applicant respectfully submits that this rejection has been overcome, and as such, that this rejection be reconsidered and withdrawn.

3. Obviousness-type double patenting rejection of claims 1-20 and 23-57 has been overcome.

Claims 1-20 and 23-57 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-45 of copending Application Ser. No. 10/854,989 in view of U.S. Patent No. 5,447,936.

Although Applicant does not acquiesce in the rejection or the characterization of the cited references, in order to expedite prosecution of the pending claims, Applicant encloses herewith a terminal disclaimer over Application Ser. No. 10/854,989. Accordingly, Applicant submits that this rejection has been overcome, and as such, respectfully requests that this rejection be reconsidered and withdrawn.

CONCLUSIONS

In view of the arguments set forth above, Applicant respectfully submits that the rejections contained in the Office Action mailed on December 23, 2004, have been overcome, and that the claims are in condition for allowance. If the Examiner believes that any further discussion of this communication would be helpful, she is invited to contact the undersigned at the telephone number provided below.

Applicant encloses herewith a Petition for a One Month Extension of Time until April 25, 2005 (April 23, 2005 being a Saturday, and April 24, 2005 being a Sunday) to respond to the Office Action dated December 23, 2004. Please charge our Deposit Account No. 08-0219 the \$60.00 fee (small entity) for this extension.

Also enclosed herewith are three terminal disclaimers. Please charge the \$195.00 total fee (three small entity terminal disclaimer fees) for these three terminal disclaimers to our Deposit Account No. 08-0219.

Please also charge our Deposit Account No. 08-0219 the \$1075.00 fee (small entity) for 43 additional dependent claims.

No other fees are believed to be due in connection with this response. However, please charge any underpayments or credit any overpayments to Deposit Account No. 08-0219.

Respectfully submitted,



Ann-Louise Kerner, Ph.D.
Reg. No. 33,523

Date: April 14, 2005
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
Tel: (617) 526-6000
Fax: (617) 526-5000